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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

PATDOCTC@fr.com

Office Action Summary

Application No.

10/848,735

Applicant(s)

SCHOMACKER ET AL.

Examiner

CHRISTINE SUNG

Art Unit

2884

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 January 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 47-90 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 47-90 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SG/US)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

Response to Amendment

1. The amendment filed on January 1, 2008 has been accepted and entered.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

3. Claims 47-61, 63-90 are rejected under 35 U.S.C. 102(e) as being anticipated by Wang (US Patent 6,537,211 B1).

Regarding claim 47, Wang discloses an apparatus (figure 13) for determining a condition of a region of a tissue sample (element 210), the apparatus comprising:

Illuminating optics (elements 214 and 216) for illuminating a region of a tissue sample with electromagnetic radiation incident at a first angle (elements 214 and 216 illuminate the same tissue area with different EM Radiation, and thus inherently illuminate at different incident angles) and subsequently illuminating the region of the tissue sample with electromagnetic radiation incident at a second angle;

Collecting optics for collecting electromagnetic radiation from the region of the tissue sample (sensor, element 220); and

A processor (element 236) configured to determine a condition of a region of the tissue sample using representative data selected from at least one of:

A first set of spectra data corresponding to the collected radiation from the region during illumination with radiation incident at the first angle (Data produced by illumination by element 214) and

A second set of spectral data corresponding to the collected radiation from the region during illumination with radiation incident at the second angle (data produced by element 216). (Note: Applicant's own disclosure, see figures 3A and 3B, discloses positioning two sources which create equal and opposite angles as sufficient for two different angles)

Regarding claim 48, Wang discloses that the process is adapted to select the representative data based at least in part on a subset of the first set of spectral data and a subset of the second set of spectral data (see figure 4).

Regarding claim 49, Wang discloses that the first set of spectral data comprises reflectance spectral data and the second set comprises reflectance spectral data (see claim 1).

Regarding claim 50, Wang discloses that at least one of the first set of spectral data and the second set of spectral data comprises fluorescence spectral data (see claim 1).

Regarding Claim 51, Wang discloses that the condition is a state of health (column 4, lines 58-67).

Regarding claim 52, Wang discloses that the state of health comprises the conditions of cancer (column 3, lines 59-62).

Regarding claim 53 Wang discloses that the tissue sample comprises at least one of the group consisting of urinary bladder, lung, and skin tissue (Column 4, lines 63-62).

Regarding claim 54, Wang discloses that the tissue sample comprises cervical tissue (column 4m line 63).

Regarding claim 55, Wang discloses that the tissue sample comprises epithelial cells (column 9, lines 10-14)

Regarding Claim 56, Wang discloses an apparatus for determining whether spectral data obtained from a region of a tissue sample are affected by an artifact, the apparatus comprising:

Illuminating optics (elements 214 and 216) for illuminating a region of a tissue sample with electromagnetic radiation incident at a first angle (elements 214 and 216 illuminate the same tissue area with different EM Radiation, and thus inherently illuminate at different incident angles) and subsequently illuminating the region of the tissue sample with electromagnetic radiation incident at a second angle;

Collecting optics for collecting electromagnetic radiation from the region of the tissue sample (sensor, element 220); and

A processor (element 236) configured to determine a condition of a region of the tissue sample using representative data selected from at least one of:

A first set of spectra data corresponding to the collected radiation from the region during illumination with radiation incident at the first angle (Data produced by illumination by element 214) and

A second set of spectral data corresponding to the collected radiation from the region during illumination with radiation incident at the second angle (data produced by element 216). (Note: Applicant's own disclosure, see figures 3A and 3B, discloses positioning two sources which create equal and opposite angles as sufficient for two different angles);

and determine whether the first set of spectral data is affected by an artifact based at least in part on a subset of the first set of spectral data and a subset of the second set of spectral data (Column 20, lines 11-24) .

Regarding Claim 57, Wang discloses that the artifact comprises a lighting artifact (column 21, lines 42-43).

Regarding claims 58-61 and 63, Wang discloses that the lighting artifact comprises glare, shadow, obstruction, blood or mucus or blood (column 13, lines 20-23).

Regarding claim 64, Wang discloses that the first set of spectral data comprises reflectance spectral data and the second set comprises reflectance spectral data (see claim 1).

Regarding claim 65, Wang discloses that the processor is further configured to obtain a third set of spectral data, and wherein the third set of spectral data comprises fluorescence spectral data (see claim 1).

Regarding Claim 66, Wang discloses that the processor is configured to determine whether the first set of spectral data is affected by an artifact by computing a difference between R1, a member of the first set of spectral data, and R2, a member of the second set of spectral data, and comparing the difference to a constant, where R1 and R2 correspond to at least approximately identical wavelengths (column 23, lines 7-24).

Regarding Claim 67, Wang discloses that the difference is a percent difference or ratio (see column 23, lines 7-24).

Regarding Claim 68, Wang discloses an apparatus for determining whether spectral data corresponding to a region of a tissue sample is affected by an artifact, the apparatus comprising:

Illuminating optics (elements 214 and 216) for illuminating a region of a tissue sample with electromagnetic radiation incident at a first angle (elements 214 and 216 illuminate the same tissue area with different EM Radiation, and thus inherently illuminate at different incident angles) and subsequently illuminating the region of the tissue sample with electromagnetic radiation incident at a second angle;

Collecting optics for collecting electromagnetic radiation from the region of the tissue sample (sensor, element 220); and

A processor (element 236) configured to determine a condition of a region of the tissue sample using representative data selected from at least one of:

A first set of spectra data corresponding to the collected radiation from the region during illumination with radiation incident at the first angle (Data produced by illumination by element 214) and

A second set of spectral data corresponding to the collected radiation from the region during illumination with radiation incident at the second angle (data produced by element 216). (Note: Applicant's own disclosure, see figures 3A and 3B, discloses positioning two sources which create equal and opposite angles as sufficient for two different angles)

and determine whether any of the first set of reflectance spectral data, the second set of reflectance spectral data, and the set of fluorescence spectral data are affected by an artifact (Column 20, lines 11-24) based at least in part on at least one of the following:

a subset of the first set of reflectance spectral data (See claim 1);

a subset of the second set of reflectance spectral data (See claim 1);

and a subset of the set of fluorescence spectral data (See claim 1).

Regarding Claim 69, Wang discloses an apparatus for determining a characteristic of a region of a tissue sample, the apparatus comprising:

Illuminating optics (elements 214 and 216) for illuminating a region of a tissue sample with electromagnetic radiation incident at a first angle (elements 214 and 216 illuminate the same tissue area with different EM Radiation, and thus inherently illuminate at different incident angles) and subsequently illuminating the region of the tissue sample with electromagnetic radiation incident at a second angle;

Collecting optics for collecting electromagnetic radiation from the region of the tissue sample (sensor, element 220); and

A processor (element 236) configured to determine a condition of a region of the tissue sample using representative data selected from at least one of:

A first set of spectra data corresponding to the collected radiation from the region during illumination with radiation incident at the first angle (Data produced by illumination by element 214) and

A second set of spectral data corresponding to the collected radiation from the region during illumination with radiation incident at the second angle (data produced by element 216). (Note: Applicant's own disclosure, see figures 3A and 3B, discloses positioning two sources which create equal and opposite angles as sufficient for two different angles)

and determine whether any of the first set of reflectance spectral data, the second set of reflectance spectral data, and the set of fluorescence spectral data are affected by an artifact (Column 20, lines 11-24);

reject at least one member of at least one of the first set of reflectance data and the second set of reflectance data determined to be affected by the artifact (column 13, lines 5-10);

and determine a characteristic of the region of the tissue sample based at least in part on at least one member of at least one of the first set of reflectance data and the second set of reflectance data not rejected (column 3, lines 59-63).

Regarding Claim 70, Wang discloses that the processor is further adapted to obtain a set of fluorescence spectral data corresponding to collected radiation from the region, and to determine the condition of the region of the tissue sample based at least in part on at least one member of at least one of the first set of reflectance data and the second set of reflectance data and at least one member of the set of fluorescence spectral data (see claim 1, Wang disclose obtaining a fluorescence image and combines the reflectance data with the fluorescence data to evaluate the image).

Regarding Claim 71, Wang discloses that the first angle and said second angle are substantially equal and opposite relative to a collection axis (see figure 1, element theta).

Regarding claim 72, Wang discloses that the said illuminating optics are configured to perform an illumination sequence in which said region is alternately illuminated at said first and second angles, and to repeat said illumination sequence at each of one or more different regions of said tissue sample (see figure 13, elements 216 and column 26, lines 1-13).

Regarding Claim 73, Wang discloses that the first angle is an average angle (Figure 12, theta m, of element 100) and said second angle is an average angle (Figure 12, theta m of element 106).

Regarding Claim 74, Wang discloses that the first angle and said second angle are substantially equal and opposite relative to a collection axis (see table 1, both sources are at the same angle, 20 degrees).

Regarding Claim 75, Wang discloses that said illuminating optics are configured to perform an illumination sequence in which said region is alternately illuminated at said first and second angles, and to repeat said illumination sequence at each of one or more different regions of said tissue sample (see figure 13, elements 216 and column 26, lines 1-13).

Regarding Claim 76, Wang discloses that the first angle is an average angle (Figure 12, theta m, of element 100) and said second angle is an average angle (Figure 12, theta m of element 106).

Regarding Claim 77, Wang discloses that the first angle and said second angle are substantially equal and opposite relative to a collection axis (see table 1, both sources are at the same angle, 20 degrees).

Regarding claim 78, Wang discloses that the illuminating optics are configured to perform an illumination sequence in which said region is alternately illuminated at said first and second angles, and to repeat said illumination sequence at each of one or more different regions of said tissue sample (see figure 13, elements 216 and column 26, lines 1-13).

Regarding claim 79, Wang discloses that the first angle is an average angle (Figure 12, theta m, of element 100) and said second angle is an average angle (Figure 12, theta m of element 106).

Regarding claim 80, Wang discloses that the first angle and said second angle are substantially equal and opposite relative to a collection axis (see table 1, both sources are at the same angle, 20 degrees).

Regarding claim 81, Wang discloses that said illuminating optics are configured to perform an illumination sequence in which said region is alternately illuminated at said first and second angles, and to repeat said illumination sequence at each of one or more different regions of said tissue sample (see figure 13, elements 216 and column 26, lines 1-13).

Regarding claim 82, Wang discloses that the first angle is an average angle (Figure 12, theta m, of element 100) and said second angle is an average angle (Figure 12, theta m of element 106).

Regarding claims 83-86, Wang discloses the limitation set forth in claims 47, 56, 68 and 69, respectively, but does not explicitly state that the first and second angles are different from each other. However, the placement of the two different illumination sources in Figure 13 (elements 214 and 216) require that the illumination angles be at least equal and opposite, for example 70 Degrees and -70 degrees, thus the angles are at least different from each other.

Regarding claims 87-90, Wang discloses detection of radiation in the visible or white light range (column 2, lines 45-56).

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).
6. Claim 62 is rejected under 35 U.S.C. 103(a) as being unpatentable over Wang (US Patent 6,537,211).

Regarding Claim 62, Wang discloses the limitation set forth in claim 60 and further discloses an obstruction (column 13, lines 20-23) but does not specify that this is a speculum and a smoke tube. However Wang teaches detecting cervical tissue (column 4, lines 62-63), and specula and smoke tubes are well known tools used to aid in the examination of the cervix. Therefore, since Wang teaches evaluating obstructions as well as detecting cervical tissue, it would have been obvious to one having ordinary skill in the art at the time the invention was made to have included evaluating an obstruction due to a speculum or smoke tube, as they are common tools for cervical examination and evaluation of such an obstruction would reduce errors in the detected data.

Response to Arguments

7. Applicant's arguments filed January 8, 2008 have been fully considered but they are not persuasive.

Applicant argues that the processor does not compensate for artifacts that may be present in one of the sets of spectral data. However, claims 47, 56, 68-69 do not require this limitation, it merely requires a processor that selects the data.

Conclusion

8. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christine Sung whose telephone number is 571-272-2448. The examiner can normally be reached on Monday- Friday 9-5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, David Porta can be reached on 571-272-2444. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Christine Sung/
Primary Examiner
Art Unit 2884

CS